February 9, 2018

Coloplast A/S
Diane Brinza
Sr. Strategic Regulatory Affairs Manager
1601 West River Road North
Minneapolis, MN 55411

Re: K173501
Trade/Device Name: Meridian Vaginal Positioning System (VPS)
Regulation Number: 21 CFR 884.4910
Regulation Name: Specialized Surgical Instrumentation for use with Urogynecologic Surgical Mesh
Regulatory Class: II
Product Code: PWK, LKF
Dated: November 10, 2017
Received: November 13, 2017

Dear Diane Brinza:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Joyce M. Whang -S

for

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K173501

Device Name
Meridian Vaginal Positioning System (VPS)

Indications for Use *(Describe)*

The Meridian VPS is a single-use device intended to assist in the position and manipulation of the vagina during gynecologic surgical procedures such as sacrocolpopexy.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY – K173501

510(K) Owner's Name:	Coloplast A/S
Legal Manufacturer Address:	Holtedam 1 3050 Humlebaek, Denmark
Contact Person:	Diane Brinza Sr. Strategic Regulatory Affairs Manager Office: 612.979.8983 Email: usdlb@coloplast.com
Address/Contact:	1601 West River Road North Minneapolis, MN 55411
Date Prepared:	9 February 2018
Trade or Proprietary Name:	Meridian Vaginal Positioning System (VPS)
Common or Usual Name:	Instrumentation for use with urogynecologic surgical mesh
Classification Name:	Specialized surgical instrumentation for use with urogynecologic surgical mesh
Classification Number:	884.4910
Product Codes:	PWK (instrumentation, surgical mesh, urogynecologic, transabdominal repair of pelvic organ prolapse) LKF (cannula, manipulator/injector, uterine)
Device Class:	II
Classification Panel:	Obstetrics/Gynecology
Predicate Device:	Restorelle Y Contour Mesh, K140116. The predicate device has not been subject to a design-related recall.

Device Description:

The Meridian® Vaginal Positioning System (VPS) is a single-use vaginal positioning device comprised of multiple polymers with an ergonomic handle and adjustable head for positioning. The head of the device consists of four main parts: a support body, a kick-out door, an adjustable cervical pin and an adjustable rib feature. The handle of the device consists of three main parts: two handle halves and an actuator knob. The Meridian Vaginal Positioning System is placed in

the vagina to stabilize and aid in the identification of vaginal structures including anterior, posterior, apex, fornices and sulci during surgical procedures such as sacrocolpopexy.

The device dimensions are listed in the table below:

Part	Dimension
Head width	45 mm
Head length	80 mm
Head thickness	30 mm
Cervical pin length	20 mm
Overall VPS length	43 cm
Kick-out door length (from tip of head to end of door)	8 cm
Kick-out door angle	40º
Rib height	5 mm

Indications for Use:

The Meridian VPS is a single-use device intended to assist in the position and manipulation of the vagina during gynecologic surgical procedures such as sacrocolpopexy.

Predicate Device Comparison:

Per the final rule published on January 6, 2017 (82 FR 1598), urogynecologic surgical mesh instrumentation has been upclassified from Class I to Class II. Because this device type has been recently upclassified, there are no cleared urogynecologic surgical mesh instrumentation devices that can serve as a predicate device. Therefore, the surgical mesh that is intended to be used with the instrumentation may serve as a predicate device.

The indications for use and technological features of the subject and predicate device are listed in the table below:

Device Characteristic	Subject device (K173501)	Predicate Device (K140116)
Indications for Use	The Meridian VPS is a single-use device intended to assist in the position and manipulation of the vagina during gynecologic surgical procedures such as sacrocolpopexy.	Restorelle Y Contour polypropylene mesh device is indicated for use as bridging material for sacrocolposuspension / sacrocolpopexy (laparotomy, laparoscopic, or robotic approach) where surgical treatment for vaginal vault prolapse is warranted.
Operating Principle	Aid in the position and manipulation of the vagina during	Transabdominal tissue reinforcement in women with pelvic organ prolapse.

	gynecologic surgical procedures	
Patient Contact	< 24 hours (tissue/bone)	Permanent (tissue/bone)
Meridian VPS Material	Multiple polymers	n/a
Mesh Material	n/a	Polypropylene
Shelf life	3 years	3 years
Sterility	Sterile, EtO	Sterile, EtO
Sterilization level	SAL 10^{-6}	SAL 10^{-6}
Packaging	PETG Retainer tray, Tyvek lid (sterile barrier) and chipboard retail box	PETG Retainer tray, Tyvek lid (sterile barrier) and chipboard retail box

The subject device has a different intended use than the predicate device, as the predicate device is a surgical mesh device indicated for the transabdominal repair of pelvic organ prolapse. The subject and predicate devices are intended to be used together, as the subject device is an accessory to a surgical mesh.

The operating principle, patient contact, and materials used are different in the subject and predicate device. The predicate device is surgical mesh whereas the subject device is used for the positioning and manipulation of the vagina during placement of the surgical mesh. The differences between the subject and predicate device raise different questions or safety and effectiveness, as we are comparing two different device types with two different intended uses. However, the subject device is an accessory to the predicate device. The differences in technological characteristics and safety and efficacy were evaluated through completion of the special controls published in the final order, as described in the performance testing section below.

Non-clinical performance testing:

The following non-clinical performance tests were performed on the subject device, per the special controls listed in 21 CFR 884.4910:

- Biocompatibility testing per ISO 10993-1 and FDA guidance document Use of International Standard ISO 10993-1, "Biological Evaluation of Medical Devices – Part 1:Evaluation and testing within a risk management process."
    - Cytotoxicity
    - Sensitization
    - Irritation
- Sterilization validation
- Package integrity testing
    - Simulated shipping and handling
    - Bubble leak testing
    - Seal strength testing
- Dimensional analysis
- Mechanical testing
    - Functional testing
    - Maximum force for head, rib, and kick out door
    - Compression

  - Bending force
  - Torque
  - Pull force
  - Side load
  - Separation force
- Shelf life Testing

Summary

The results of the performance testing described above demonstrate that the Meridian Vaginal Positioning System is as safe and effective as the predicate device and supports a determination of substantial equivalence.